

**Notice of Allowability**

Application No.

10/025,506

Examiner

Sharon Kennedy

Applicant(s)

MCGUCKIN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_.
2. ☒ The allowed claim(s) is/are 1-25 and 28-30.
3. ☒ The drawings filed on December 19, 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date all
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, 28-30, drawn to a catheter, classified in class 604, subclass 264.
- II. Claims 26-27, drawn to a catheter in combination with a trocar, classified in class 604, subclass 164.13.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the particular lumen structure of the dialysis catheter. The subcombination has separate utility such as an irrigation catheter.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Neil Gershon on July 19, 2004 a provisional election was made without traverse to prosecute the invention of Group I,

claims 1-25, 28-30. Claims 26-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Neil Gershon on July 19, 2004.

The application has been amended as follows:

#### **In the Specification:**

On page 15, line 5, change "32" to --42--.

#### **In the Claims:**

Please cancel claims 26-27.

Please amend claims 1 and 28 as follows:

Claim 1, line 1, change "dialysis" to --hemodialysis--.

Claim 28, line 1, after "A" insert --hemodialysis--.

***Allowable Subject Matter***

Claims 1-25, 28-30 are allowed.

The following is an examiner's statement of reasons for allowance: Regarding claims 1 and 28, these claims have been amended to a hemodialysis catheter. This amendment breathes "life and vitality" into the preamble of the claims and limits the structure to a hemodialysis catheter. Although there are many hemodialysis catheters having similar lumen structures, none shows the specific structures of applicant's invention. The importance of applicant's lumen structure is pointed out in applicant's published application, page 2, paragraph [0028]. As stated therein, there is a large body of art dedicated to optimizing the blood flow through the catheter body while still keeping the catheter as small as possible to facilitate insertion thereof. Further, a balance must be achieved while still maintaining the structural integrity of the catheter. The present invention accomplishes these objectives. The two most relevant patents to the structure are Sharkawy, US 5,012,044 and Ekholmer, US 4,717,379, however, neither of these patents are hemodialysis catheters, nor are they intended to withdraw substances from the body, and it would not be obvious to place that lumen structure on any of the hemodialysis catheter patents cited by applicant.

Regarding claims 17 and 21, these claims require a first central lumen and first and second longitudinally extending lumens independent of the first lumen (and a third independent lumen in claim 21), in combination with a stiffening insert which also has a

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lumen. The closest prior art is the patent to Bogue et al., US 4,270,535, however, that catheter shows only a central lumen 14 surrounded by an outer lumen 16. The stiffening insert having the lumen is shown by removable trocar 17. The combination of the trocar 17 and catheter in this relationship is sometimes termed an "over the needle" type of catheter insertion, however, none of the prior art discloses or suggests the structures recited in applicant's claims.

A few other patents of interest are: Taricco, US 3,833,003; Howes, US 4,894,057; Dake, US 4,927,418; Powers, US 5,810,789; Hattler et al., US 4,406,656; Smith, US 2,460,473; Makower et al., US 5,380,290, all of the Geoffrey Martin et al patents, especially US 5,797,869; Harkrider, US 6,328,730; Laub, US 4,808,163.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 703/305-0154. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703/308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sharon Kennedy  
Primary Examiner  
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